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Additional Curing Methods for Destroying Trichinae; Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318 and 320

[Docket No. 89-025F]

RIN 0583-AA43

Additional Curing Methods for Destroying Trichinae

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations which concern processing oval (flattened) sausage and dry-cured ham and port shoulders to destroy trichinae (Trichinella spiralis larvae) which may be encysted in the pork meat component, as follows: a footnote in Method No. 6 for sausages has been amended to change the manner of determining the drying time for flattened sausages; a preface to the ham methods has been added to assure uniform calculation of processing days; Method No. 1 for dry-cured hams has been amended to permit additional combinations of drying times and temperatures already permitted in Method No. 3; Method No. 2 for dry-cured hams has been removed, since it is no longer used. Method No. 3 for dry-cured hams has been extensively amended to accommodate some traditional processing methods, to remove the permission to pump these hams, and to provide greater safety. Method No. 4 is being published as a new trichina destruction provision for ham which would permit establishments to substitute potassium chloride for salt in the curing mixture based on data which substantiates that particular curing mixture. In addition, the Agency is amending the regulations in response to petitions to provide additional trichina destruction methods for dry sausage and dry-cured ham. These methods consist of one trichina destruction method for two size ranges of dry sausage and two trichina destruction methods for dry-cured ham. Finally, a few nonsubstantive changes have been made for clarity.

EFFECTIVE DATE: July 22, 1992. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 22, 1992.

FOR FURTHER INFORMATION CONTACT: William C. Smith, Director, Processed Products Inspection Division, Science & Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 720-3840.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This final rule is issued in conformance with Executive Order 12291, and has been determined to be not a "major rule." It would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) from imposing any ingredient requirements or requirements with respect to the operations of any establishment at which inspection is provided under title I of the FMIA which are in addition to, or different than, the requirements of the FMIA. States and local jurisdictions, may, however, exercise concurrent jurisdiction over meat products that are outside official establishments for the purpose of preventing the distribution of meat products that are misbranded or adulterated under the FMIA, or, in the case of their entry into the United States. Under the FMIA, states that maintain meat inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the FMIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

This rule is not intended to have retroactive effect, and there are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule. However, the administrative procedures specified in 9 CFR 306.5 must be exhausted prior to any judicial challenge of the application of the provisions of this rule.

Effect on Small Entities

The Administrator has determined that this rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Approximately 480 establishments are producing dry sausage and/or dry-cured hams, a majority of which are small businesses. The Federal meat inspection regulations require that processed pork products be treated to destroy trichinae by one of several prescribed methods. This final rule provides three additional methods of treatment to destroy trichinae in certain cured pork products, as petitioned for by pork producers and, thus, gives pork producers additional flexibility in choosing a destruction method. Use of one of these additional methods in lieu of one of the methods currently prescribed is voluntary. Some country ham producers may have to change their processes slightly or make a minimal investment in equipment amounting to several hundred dollars. The Agency has determined that this is not a significant impact on these small producers. The amendment to Method No. 1 and the requirement for oval sausages were requested by processors and are voluntary, so they have a negligible effect on the industry. The amendment to Method No. 3 now accommodates some traditional processing procedures such as bag curing and it addresses the use of ambient temperature for drying, thus giving processors clearer and more flexible instructions for these uses. However, the amended Method No. 3 removes drying times at temperatures below 75 °F because research showed them to be inadequate for the times tested; this will affect 10 to 109 establishments that in 1985 reported using a drying temperature less than 75 °F and may affect another 7 establishments reported to be using temperatures less than 75 °F in combination with higher temperatures. Method No. 4, permitting the use of potassium chloride, is another additional method. It does not preclude any present method, can be used with simple technology, and partially answers a few complaints that processors receive concerning the sodium content of their products. It has a negligible effect on small entities. The brine concentration analysis required by Methods 5 and 6 for dry-cured hams will cost approximately $15 to $30 for each composite sample. The approximate cost would be $360 initially and $30 per quarter thereafter. However, these methods and the included tests are only alternatives to the methods now available and permit the application of less salt if a higher percentage is absorbed, resulting ultimately in an equivalent amount of salt in the meat. Hence, the end product test (for brine concentration) is needed rather than the

more traditional composition requirement of percent salt.

Paperwork Requirements

This rule requires dry-cured ham manufacturers wishing to utilize methods 5 and 6 to have a process control program to monitor and control the internal brine concentrations, the minimum drying times and temperatures, and the minimum total processing times of the hams. The process control program must be filed in the establishment and available for review by program employees. The manufacturer is required to use an FSIS accredited laboratory, under the provisions of 9 CFR 318.21, to conduct analyses for salt and water content for each production lot tested. The manufacturer will then use the laboratory results to perform a calculation to ensure that the internal brine concentration, a measure of the amount of salt in the product in relation to the water, is at least 6 percent. FSIS has determined that a minimum brine concentration of 6 percent provides enough salt to destroy any trichinae present in the product. The laboratory results and the results of the calculations must be filed as part of the process control program. These recordkeeping requirements have been approved by the Office of Management and Budget (OMB) under control number *0583–0065.*

Background

Trichinella spiralis or "trichina" is a parasitic worm that causes the disease trichinosis in virtually all warm-blooded animals. The most common way for humans to acquire trichinosis is to ingest undercooked pork infested with trichina cysts. Trichinosis resulting from pork consumption is far less prevalent today than in the past in part because USDA requires that all pork in ready-to-eat products be either tested for trichinae or treated to destroy or inactivate trichinae.

Since the early part of this century, USDA has required manufacturers of ready-to-eat pork products to treat them for trichinae with one of several prescribed methods. Trichina cysts can be killed by heat and they can also be killed by sufficient freezing, salting, drying, and aging. Although most ready-to-eat pork products on the market are cooked, some are made safe to eat by freezing and others by a combination of salting, drying, and aging.

On March 10, 1983, FSIS published a proposed rule in the **Federal Register** (48 FR 10065) to permit additional trichina destruction treatment methods consisting of prescribed times and internal product temperatures for freezing, combinations of smoking temperature and drying temperature for processing hams and pork shoulders, and alternate sausage drying times based on salt content, sausage diameter, and fermentation or smoking temperature and time. The final rule was published on February 7, 1985 (50 FR 5226) and became effective on August 6, 1985. On that effective date, all trichina destruction methods not in the regulations were rescinded. Many small country ham manufacturers objected to the final rule. They asserted that they were using time-tested methods and that there was no history or illness associated with their product. FSIS considered these claims to have merit and published a partial waiver of the final rule on June 18, 1985 (50 FR 25202).

Subsequently, FSIS worked with other USDA scientists to develop a general research protocol for gathering information about the mechanism of killing trichinae by curing. The research was conducted at Texas A & M.

As a result of this research, a proposal was published on April 20, 1989 (54 FR 15946). That proposal, finalized here, changed the present Method No. 3 of producing dry-cured hams and pork shoulders in a number of ways. The regulation prescribing the method is now divided into paragraphs according to the different stages of processing. A minimum percentage of salt content is specified for the curing mixture. The regulation does not specify an amount of salt in relation to the amount of meat, except in the case of the bag cure. (A bag cure is the wrapping of a ham and all of its cure in kraft paper and hanging it individually). There are now mandatory cure contact times and total curing times. For the first time, the bag cure is specifically recognized and accepted. Also, in recognition of the actual practices in the production of country ham, the regulation provides three different schedules of drying times, depending on whether the establishment elects to (1) dry the product in a temperature controlled room, (2) not control the room temperature, but monitor it and alter the drying times accordingly, or (3) ignore the temperature and operate solely by the calendar. For all establishments which operate on the basis of drying temperature, whether controlled or not, the most significant change is the removal from the drying time/temperature table of all temperatures below 75 °F. This came about as a result of the Texas A & M research which showed that lower temperatures were less effective than originally thought.

Although the changes to Method No. 3 are the most important part of the 1989 proposal, there are several other changes as well. Method No. 2 is rescinded because it is no longer used; the drying requirements for oval sausages are eased, based on the application of basic physical principles and data submitted by a manufacturer, and Method No. 4 is established to permit manufacturers to substitute potassium chloride for salt (sodium chloride) in the curing mixture based on data substantiating that particular process.

While the research that served as the basis for the 1989 proposal was being conducted, three manufacturers petitioned the Agency for amendments to the trichina regulations, asking for additional treatment methods. In response to the Agency's replies, the manufacturers sponsored additional research at two State universities. These projects were not completed until after the publication of the 1989 proposal and, thus, were not included in that publication. They were completed soon afterward and were the basis for three new proposed methods published on January 7, 1991 (56 FR 503). One of the new methods was for dry sausage and two were for prosciutto-type dry-cured hams. That proposal also contained a cautionary statement at the beginning of § 318.10(c) advising processors that these following treatments, while adequate for killing trichinae, may not be rigorous enough to kill pathogenic bacteria.

Discussion of Comments

FSIS received 14 comments on the proposed rule for processing country hams and 4 comments on the proposed rule for processing prosciutto and dry sausage. The comments and responses are listed below, first on the proposed cautionary statement and then in order of occurrence of the relevant provisions in the final rule.

The Cautionary Statement

Two representatives of industry associations commented extensively against the proposed cautionary statement. Both disagreed with the background statement "that some manufacturers may not recognize that the trichina treatment does not preclude adulteration by bacterial pathogens." The first comment stated that including the cautionary statement seemed to assume widespread ignorance throughout the industry regarding the control of trichinae versus control of pathogenic bacteria. The commenter emphatically did not agree.

Another point was that the American Meat Institute publication Good Manufacturing Practices: Fermented Dry and Semi-dry Sausages has resulted in the production of safe products free from adulteration caused by pathogenic bacteria, hence no cautionary statement is needed.

A third point was that the incidences cited by FSIS as evidence for the necessity of the cautionary statement were insufficient and probably two of them were caused by post-processing contamination.

A fourth point was that FSIS has ample regulatory authority to proceed against products adulterated by bacterial pathogens.

The Agency agrees that the cautionary statement, on balance, is best removed from the trichinae control section of the regulations as essentially irrelevant to the control of trichinae. Since the statement is being removed, and the microbiological concerns are addressed in present rules and will be further addressed in future rules as needs require, the other points need not be addressed here, except to state that the statement was intended to be helpful, not to imply widespread ignorance on the part of industry.

Comment on Sausage Treatment Methods

There was one comment by a representative of a professional association on the proposed sausage treatment method (Method No. 7). The commenter's primary concern was that the proposal used chamber temperature rather than internal product temperature. The commenter stated that, because sausages often contain meat from the diaphragm and masseter muscles (sites most likely to contain large numbers of trichina cysts in heavily infected pigs), process control is important.

The Agency agrees with the commenter's concerns and voiced the same concern when the validation protocol was first proposed by the manufacturer. The Agency was concerned that product internal temperature and room temperature would not be correlated. However, the petitioner addressed the Agency's concerns, and the data showed that room temperature was sufficiently related to internal product temperature to allow determination of the destruction of all trichinae in heavily infected pork.

The Agency also reorganized the holding times and temperatures so that, for clarity, they are all included in the tables.

Comments on Ham and Pork Shoulder Methods

One commenter questioned whether any new treatment methods were needed for country ham. He stated that there should be no trichina treatment requirement for country hams because they are generally cooked before eating.

The Agency disagrees with the comment; the requirement for treating all dry-cured hams, including country hams, for trichina destruction was fully promulgated as a part of the dry-cured ham standard in § 319.106, in response to an industry petition. Furthermore, there is considerable evidence that some consumers eat country ham without any cooking either as a common practice or as low cost alternative to prosciutto.

The same comment further asserted that there was no epidemiological data to support the need for trichina treatment of country hams, and he noted that of the over 100 country ham processes that FSIS reviewed, only 2 were found to be unacceptable. His apparent conclusion is that the present system works and no change is needed.

The Agency disagrees with the comment's premises. The commenter is correct in that only two processes were considered unacceptable; however, a number of the others were borderline on acceptability and suggestions were made to improve the process safety. The exercise demonstrated that a system of informal approvals based on limited research data is error-prone and is unacceptable.

One commenter recommended that processors be permitted to continue using the 180 day ambient temperature process inferred from the now rescinded MPI Bulletin 742. Another commenter further recommended withdrawing the proposal and permit processors to continue to use all the times and temperature in MPI Bulletin 742.

The Agency disagrees. The MPI Bulletin was shown to have had errors which were corrected in the 1985 final rule; those errors consisted of vagueness, requiring too short a drying time for the lower drying temperatures and the inference of a permitted 180 day, ambient temperature process provision. This rule further refines the times and temperatures in that bulletin which was rescinded in 1985.

Two comments from country ham processing associations recommended that FSIS conduct further research before proceeding with final rulemaking. One recommended that all present procedures be permitted until definitive testing can be accomplished.

The Agency sympathizes with the desire for definitive testing; however, it is impractical. The Agency has reviewed the testing results and information on which this rule is based, and has determined that it is sufficient to objectively establish the safety of this rule.

Two comments from country ham processor associations were on the adequacy of the research conducted at Texas A & M. One commented that the researchers did not consider the effect of percent salt in the curing mixture and expressed the belief that the percent salt in the mixture has a direct effect on trichina death. The other commenter said that the Texas A & M research used only three temperatures, instead of the full range of temperatures in MPI Bulletin 742.

The Texas A & M research addressed all of the variables necessary to construct this processing rule; additional variables, such as those suggested by the commenter, did not appear to be justified by the additional expense necessary to establish their validity. The Agency chose three temperatures to confirm (or refute) the time-temperature table in Method No. 3 (which was an amendment of the table in MPI Bulletin 742); additional temperatures would have been useful but not cost effective. The times and temperatures in the MPI Bulletin were not based on research on each temperature, instead they were based on several temperatures and times and the intermediate times and temperatures were interpolated according to acceptable scientific methods. Further, research subsequent to the publication of MPI Bulletin 742 showed the times at lower temperatures were not sufficient for safety; therefore, these were increased in Method No. 3. Because the Texas A & M research showed that the Method No. 3 time for 50 °F was inadequate, it is being removed with this amendment. Post-Texas A & M research has indicated that at 50°F, approximately 150 days are required to kill trinchinal cysts. With the submission of more data based on more research, this temperature can possibly be reinstituted into Method No. 3 with an appropriate amount of drying time.

Three commenters recommended removing the option of brine injection for Method No. 3.

The Agency included the brine injection option since it was permitted, but not mandated, in Method No. 1 and to provide flexibility to processors who may wish to use that option. However, since the standard of identity in § 319.106 prohibits brine injection, permitting it in Method No. 3 has caused some confusion among processors and the public. Few or no processors use

that option and the Agency received no comment against removing Method No. 2 in which brine injection is mandated. Therefore, the Agency is amending the proposed Method No. 3 by removing the brine injection option. Processors who may wish to use brine injection for a dry salt cured ham can still use that option in Method No. 1.

Four commenters proposed that the equalization temperature of Method No. 3 for hams and pork shoulder picnics be raised from a maximum of 55 °F to maximum of 65 °F. The rationale for their proposal was that their equipment does not operate as efficiently at 55 °F.

The Agency proposed the 55 °F limit as a maximum temperature to restrict potential pathogenic bacterial growth. Since the proposal, additional information has become available to better judge the effect of a higher temperature. The Agricultural Research Service (ARS) has developed a computer modeling program to better estimate the potential growth of various pathogens under different conditions of temperature, salt, acidity, atmosphere, and nitrite content. Using that modeling program, the Agency has determined that 55 °F is indeed safer than 65 °F, however, the lag and generation times at 60 °F are so long that the potential for growth on a dry-cured ham at 60 °F is small. Accordingly, the Agency is amending the proposed equalization temperature from a maximum of 55 °F to a maximum of 60 °F.

There were four comments on the proposed Table 5 in Method No. 3. One commenter proposed 60 °F, instead of 75 °F, as the minimum temperature for that table.

The Agency agrees that 60 °F can be a minimum drying temperature under some circumstances; since subsequent research done on prosciutto ham processing has shown that a 150 day drying period can be safe. However, at this time the use of lower drying temperatures is predicated upon careful control of the internal brine concentration. Therefore, processors wishing to use lower drying temperatures can use Method No. 5.

A commenter asked for clarification as to whether processors using ambient temperature drying and temperature recorders, as permitted in Method No. 3 for hams and pork shoulder picnics, could release product before August 31.

The answer is yes. The final rule is specific: Processors can use any of three procedures for drying, and the last two of these procedures use uncontrolled or ambient temperatures. The last drying procedure requires no temperature monitoring and permits the processor to dry by the calendar but product may not be released before August 31. The other ambient temperature drying procedure requires monitoring the internal product temperature but permits release when the time-temperature requirements of Table 5 are attained; they may be at any time during the year.

A commenter recommended allowing temperature combinations to be used without extending the requirement to 1.5 times the number of days that are otherwise required.

The use of these temperature combinations permits processors greater flexibility than does the present rule, in that it permits permutations of more than two temperatures and does not require the processor to begin with the higher temperature as Table 6 did. Although the trichina death studies have been done with constant temperatures, the use of permutations of temperatures (and their associated times), in the former Table 6 and in the provision of this rule, appears warranted since the death kinetics follow the law of mass action (rate = time × Temperature × concentration). However, because the trichina death kinetics of temperature permutations have not been researched, the Agency increased the permutated time by 1.5 to add a conservative amount of safety margin. It may well be that some or all of the added safety margin is unneeded. However, until research shows that to be true, the Agency will retain the safety margin. Therefore, the final rule contains the added time.

Two commenters objected to requiring the entire months of June, July, and August for drying hams by a non-monitored ambient temperature procedure as is permitted in Method No. 3 for hams and pork shoulder picnics. One commenter believed it was more drying time than needed and the other claimed it unfairly restricts business. Neither comment was accompanied by substantiating evidence that less drying time at ambient temperature is needed.

The Agency disagrees with the comments; the Agency carefully reviewed and evaluated the available data on trichina destruction and weather in country ham processing areas and proposed a method which seemed to be both safe and in accordance with traditional procedures. No procedure that is required for public safety can be reasonably claimed to unfairly restrict business. Those processors who wish to release their hams sooner, but not use a controlled temperature drying chamber, can use the option of recording the hams' internal temperatures.

One commenter decried the use of potassium chloride (KCl) for personal health reasons. The commenter is sensitive to excessive potassium and claimed that restaurants list the hams only as salt cured and not KCl cured.

The Agency is aware of the issue to which the comment refers, but, due to limited resources, relies on local health authorities for the accurate labeling of restaurant food. The Agency will notify local health authorities that dry-cured hams with high levels of potassium may appear on the market. The local authorities in turn should inform retail purveyors that they have a duty to convey that information to their customers.

One commenter cautioned that his experiments had shown an adverse flavor may occur from using 50 percent KCl.

The Agency has taken no position on the flavor of Country Hams since there is a wide range of organoleptic quality among the various processors. It may be that consumers of these hams will reject KCl cured hams or may prefer them. In any case the Agency has determined that the use of KCl is safe with respect to trichina safety. Also, the Agency is permitting a maximum of 50 percent KCl substitution; processors have the option of using less and adjusting their curing ingredients to achieve a product desired by their consumers.

A meat scientist asked, concerning Method No. 4, if the ionic concentration of sodium chloride (NaCl) and KCl would be used or the actual salt penetration rate.

The answer is that the control on NaCl and KCl was based on the control used in the experiment which was the physical weight of the compound applied to the meat. Therefore, neither ionic concentration nor salt penetration was used because these are based on the amount of salt taken up by the meat. In addition, this control is easier to administer and regulate.

FSIS received five comments regarding the curing times proposed for Method No. 4 for hams and pork shoulder picnics, permitting the substitution of potassium chloride (KCl) for up to half the required salt (sodium chloride—NaCl). All of the comments referred to North Carolina State research that showed that KCl increased the rate of cure penetration; thus, a longer curing period should not be required. Three of the comments also recommended prescribing only two overhauls (three applications), not the three overhauls the researcher used. (An overhaul is the turning over of a unit of product for the application of additional cure).

FSIS proposed the same procedure used by the North Carolina researcher. This was done because the research showed only that a procedure using KCl was effective by the end of the process in destroying trichinae, but not that the rate of destruction was equivalent to that of NaCl. However, since the publication of the proposal, the researcher has performed more research, and supplied more data so that with that additional information, FSIS is now amending Method No. 4 to permit two or three overhauls.

A researcher commented that Method No. 4 ought to permit soaking to remove excess cure from hams after the curing period instead of only rinsing with tap water. He noted that since Method No. 1 permits soaking, some processors prefer that to rinsing.

The Agency disagrees because no supporting evidence was submitted to demonstrate that soaking did not result in a lower brine concentration. Indeed, the Agency notes that the researcher's latest report, submitted this May, was based on rinsing with tap water, not soaking. The Agency is willing to review data which shows that soaking yields an equally safe product.

A commenter asked how the low temperature long time drying procedures used by traditional prosciutto manufacturers will be accommodated.

At the time the first proposal was published, there was no provision for the long time low temperature drying used by traditional prosciutto manufacturers, however, there was research underway to validate those procedures. That research has been completed, and a proposal covering these type processes has been published and is incorporated into this final rule as Method No. 5.

A comment was received on the proposed methods Nos. 5 and 6 for dry-cured hams. The comment, from a meat scientist, questioned the need for 6 percent brine in the biceps muscle, since his research had shown trichina destruction at lower brine concentrations, and the Texas A&M research also showed trichina destruction at lower brine concentrations, than that proposed in these two methods.

The Agency agrees that lower brine concentrations have been shown to be lethal to trichinae. However, these processes were developed by prosciutto manufacturers whose products are generally more salty than country hams. The data they furnished indicated that, at the times and temperatures they wished to use, the 6 percent brine concentration was a needed processing factor. At any rate, for these processes, with these times and temperatures, this is the only supporting data that the Agency has.

In addition to the changes made pursuant to the comments, the Agency is making a few nonsubstantive changes for clarity. Therefore, the Agency is amending the regulations as follows:

Final Rule

For the reasons discussed in the preamble, FSIS is amending Parts 318 and 320 of the Federal meat inspection regulations as set forth below.

List of Subjects in 9 CFR Parts 318 and 320

Incorporation by reference, Meat inspection.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority for part 318 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. In § 318.10, paragraph (c)(3)(i) is amended by revising the text of footnote 1 to Table 3A and adding a new method No. 7, and paragraph (c)(3)(iv) is revised to read as follows:

§ 318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.

* * * * *

(c) * * *

(3) * * *

(i) * * *

Table 3A

* * * * *

[1] The drying room times for flattened or oval sausages shall use a diameter derived by measuring the circumference and dividing by 3.14 (pi).

* * * * *

Method No. 7, Dry Sausages. (A) *General Requirements.* The establishment shall use meat particles reduced in size to no more than 1/4 inch in diameter. The establishment shall add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it uniformly throughout the product. The establishment shall hold, heat, and dry the product according to paragraph (B) or (C) below.

(B) *Holding, Heating, and Drying Treatment, Large Sausages.* Except as permitted in (C) below, the establishment shall subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

TREATMENT SCHEDULE FOR SAUSAGES 105 MILLIMETERS (4 1/16 INCHES) OR LESS IN DIAMETER

Minimum chamber temperature		Minimum time (hours)
(°F)	(°C)	
50	10	12
90	32.2	1
100	37.8	1
110	43.3	1
120	48.9	1
125	51.7	7

Following the preceding treatment, the establishment shall dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 7 days.

(C) *Heating and Drying Treatment, Small Sausages.* Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

TREATMENT SCHEDULE FOR SAUSAGES 55 MILLIMETERS (2 1/8 INCHES) OR LESS IN DIAMETER

Minimum chamber temperature		Minimum time (hours)
(°F)	(°C)	
50	10	12
100	37.8	1
125	51.7	6

Following the preceding heat treatment, the establishment shall dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 4 days.

* * * * *

(c) * * *

(3) * * *

(iv) *Hams and pork shoulder picnics.* In the curing of hams and pork shoulder picnics, one of the methods below shall be used. For calculating days per pound, the establishment shall use the weight of the heaviest ham or picnic in the lot.

Method No. 1. The hams and pork shoulder picnics shall be cured by a dry-salt curing process not less than 40 days at a temperature no lower than 38 °F. The products shall be laid down in salt, not less than 4 pounds to each hundredweight of product, the salt being applied in a thorough manner to the lean meat of each item. When placed in cure, the products may be pumped with pickle if desired. At least once during the curing process, the products shall be overhauled (turned over for the application of additional cure) and additional salt applied, if necessary, so that the lean meat of each item is thoroughly covered. After removal from cure, the products may be soaked in water at a temperature not higher than 70 °F for not more than 15 hours, during which time the water may be changed once, but they shall not be subjected to any other treatment designed to remove salt from the meat except that superficial washing may be allowed. The products shall finally be dried or smoked at a

time and temperature not less than a combination prescribed in Table 5 of Method No. 3.

Method No. 2. [Reserved]

Method No. 3. (A) *Curing.* (Other than bag curing): Establishments shall cure hams and shoulders by using a cure mixture containing not less than 70 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Total curing time consists of a mandatory cure contact time and an optional equalization time.

(B) *Cure Contact Time.* This is the cure contact period, during which the establishment shall keep exposed muscle tissue coated with the cure mixture at least 28 days but for no less than 1.5 days per pound of ham or shoulder. Overhaul is optional so long as the exposed muscle tissue remains coated with curing mixture.

(C) *Equalization.* The establishment may provide an equalization period after the minimum cure contact period in (B) above to permit the absorbed salt to permeate the product's inner tissues. Equalization is the time after the excess cure has been removed from the product at the end of the cure contact period until the product is placed in the drying room and the drying period begins. The total curing time (equalization plus cure contact) shall be at least 40 days and in no case less than 2 days per pound of an uncured ham or shoulder.

(D) *Removing Excess Cure.* After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(E) *Bag Curing.* Bag curing is a traditional ham curing technique in which the manufacturer wraps the ham and all of the cure mixture together in kraft paper then hangs them individually. The paper keeps the extra cure mixture in close contact with the product making reapplication of salt unnecessary, and it protects the product from mites and insects. Establishments may employ the bag curing method as an alternative to (A) through (D) above. An establishment which elects to use the bag curing method shall apply a cure mixture containing at least 6 pounds of salt per 100 pounds of uncured product. The establishment shall rub the curing mixture into the exposed muscle tissue, pack the hock region with the curing mixture, and use uncoated wrapping paper to wrap the product together with any remaining curing mixture. The bag cured product shall remain wrapped throughout the curing period and may or may not remain wrapped during the drying period. In any case, the curing period shall be at least 40 days but not less than 2 days per pound of an uncured ham or shoulder. After curing, the cured product shall be exposed to a drying time and temperature prescribed in Table 5.

(F) *Curing Temperature.* During the curing period the establishment shall use one of the following procedures:

(1) The establishment shall control the room temperature at not less than 35 °F (1.7 °C) nor greater than 45 °F (7.2 °C) for the first 1.5 days per pound of an uncured ham or shoulder, and not less than 35 °F (1.7 °C) nor greater than 60 °F (15.6 °C) for the remainder of the curing period.

(2) The establishment shall monitor and record daily product temperature. The room temperature need not be controlled but days on which the product temperature drops below 35 °F (1.7 °C) shall not be counted as curing time. If the product temperature exceeds 45 °F (7.2 °C) within the first period of 1.5 days per pound of an uncured ham or shoulder or if it exceeds 69 °F (15.6 °C) for the remainder of the curing period, the establishment shall cool the product back to the 45 °F (7.2 °C) maximum during the first period or 55 °F (12.8 °C) maximum during the remainder of the period.

(3) The establishment shall begin curing product only between the dates of December 1 and February 13. The room temperature need not be controlled, but the establishment shall monitor and record daily room temperatures, and days in which the room temperature drops below 35 °F (1.7 °C) shall not be counted as curing time.

(G) *Drying.* After the curing period, establishments shall use one of three procedures for drying:

(1) The establishment shall subject the product to a controlled room temperature for a minimum time and minimum temperature combination prescribed in Table 5 or for a set of such combinations in which the total of the fractional periods (in column 4 of Table 5) exceeds 1.5.

(2) Establishments using uncontrolled room temperatures shall monitor and record the internal product temperature. The drying period shall be complete when, from the days which can be counted as curing time, one of the time/temperature combinations of Table 5 is satisfied or when the total of the fractional values for the combinations exceeds 1.5.

(3) Establishments using uncontrolled room temperatures shall dry the product for a minimum of 160 days including the entire months of June, July, and August. This procedure is obviously dependent on local climatic conditions and no problem exists with respect to current producers who use this procedure. Future applicants shall demonstrate that their local monthly average temperatures and the local monthly minimum temperatures are equal to or warmer than the normal average temperatures and normal minimum temperatures compiled by the National Oceanic and Atmospheric Administration for Boone, North Carolina, station 31–0977, 1951 through 1980.

MONTHLY TEMPERATURES (°F) FOR BOONE NC, 1951–1980

Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sep.
Normal average temperatures								
32.2	34.1	41.3	51.2	59.1	65.1	68.3	67.5	61.6
Normal minimum temperatures								
22.8	24.2	30.8	39.6	48.1	54.7	58.5	57.6	51.6

Drying Times and Temperatures for Trichina Inactivation in Hams and Shoulders

TABLE 5.—MINIMUM DRYING DAYS AT A MINIMUM TEMPERATURE*

Minimum Drying Temperature		Minimum days at drying temperature	Fractional period for one day of drying
Degrees fahrenheit	Degrees centigrade		
130	54.4	1.5	.67
125	51.7	2	.50
120	48.9	3	.33
115	46.1	4	.25
110	43.3	5	.20

TABLE 5.—MINIMUM DRYING DAYS AT A MINIMUM TEMPERATURE*—Continued

Minimum Drying Temperature		Minimum days at drying temperature	Fractional period for one day of drying
Degrees fahrenheit	Degrees centigrade		
105	40.6	6	.17
100	37.8	7	.14
95	35.0	9	.11
90	32.2	11	.091
85	29.4	18	.056
80	26.7	25	.040
75	23.9	35	.029

* Interpolation of these times or temperatures is not acceptable; establishments wishing to use temperatures or times not in this Table shall first validate their efficacy as provided by 318.10(c)(4) of this section.

Method No. 4.

(A) Cure: Establishments shall cure hams and shoulders by using a cure mixture containing not less than 71.5 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Establishments may substitute potassium chloride (KCl) for up to half of the required salt on an equal weight basis.

(B) *Curing.* Establishments shall apply the cure at a rate not less than 5.72 pounds of salt and KCl per hundred pounds of fresh meat. The cure shall be applied in either three or four approximately equal amounts (two or three overhauls) at separate times during the first 14 days of curing.

(C) *Cure Contact Time.* Establishments shall keep the product in contact with the cure mixture for no less than 2 days per pound of an uncured ham or shoulder but for at least 30 days. Establishments shall maintain the curing temperature at no less than 35°F (1.7°C) during the cure contact time.

(D) *Equalization.* After the cure contact period, establishments shall provide an added equalization period of no less than 1 day per pound of an uncured ham or shoulder but at least 14 days. Equalization is the time after the excess cure has been removed from the product, the end of the cure contact period, and before the drying period begins. Establishments may substitute additional cure contact days for an equal number of equalization days.

(E) *Removing Excess Cure.* After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(F) *Drying.* After the curing period, establishments shall use one of the controlled temperature methods for drying listed in Method No. 3 of this subparagraph.

Method No. 5

(A) *Curing.* The establishment shall cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.

Percent brine = 100 × [salt] / ([salt] + [water])

The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration in the ham.

(B) *Drying and Total Process Times.* The establishment shall dry the cured ham at a minimum temperature of 55 °F (13 °C) for at least 150 days. The total time of drying plus curing shall be at least 206 days.

(C) *Ensuring an Acceptable Internal Brine Concentration.* (1) To establish compliance, the establishment shall take product samples from the first 12 lots of production as follows: From each lot,

(i) One sample shall be taken for each 5 or more hams;

(ii) Each sample shall be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency shall consider other method(s) of sampling the dry-cured hams to determine the minimum internal brine concentration, as long as the establishment proposes it and submits data and other information to establish its sufficiency to the Director of the Processed Products Inspection Division;

(iii) Each sample shall weigh no less than 100 grams;

(iv) The samples shall be combined as one composite sample and sealed in a water vapor proof container;

(v) The composite sample shall be submitted to a laboratory accredited under the provisions of § 318.21 to be analyzed for salt and water content using methods from the "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC)," 15th Edition, 1990, Section 983.18 (page 931) and Section 971.19 (page 933) which are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, suite 400–BW, 2200 Wilson Boulevard, Arlington, VA 22201–3301. Copies may be inspected at the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or at the Office of the Federal Register, 1100 L Street, NW, room 8401, Washington, DC. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment shall freeze the composite sample immediately after the samples are combined;

(vi) Once the laboratory results for the composite sample are received, the manufacturer shall calculate the internal brine concentration by multiplying the salt concentration by 100 and then dividing that figure by the sum of the salt and water concentrations;

(vii) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance shall be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested shall be held until the establishment brings the lot into compliance by further processing.

(2) To maintain compliance, the establishment shall take samples, have the samples analyzed, and perform the brine calculations as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance shall not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment shall develop and propose steps acceptable to FSIS to ensure that the process is corrected.

(3) Accredited laboratory results and the brine calculations shall be placed on file at the establishment and available to Program employees for review.

Method No. 6

(A) *Curing.* The establishment shall cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.

Percent brine = 100 × [salt] / ([salt] + [water])

The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration.

(B) *Drying and Total Process Times.* The establishment shall dry the cured ham at a minimum temperature of 110 °F (41 °C) for at least 4 days. The total time of drying plus curing shall be at least 34 days.

(c) *Ensuring an Acceptable Internal Brine Concentration.*

(1) To establish compliance the establishment shall take product samples from the first 12 lots of production as follows: From each lot,

(i) One sample shall be taken from each of 5 or more hams;

(ii) Each sample shall be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider

other methods of sampling the dry-cured hams to determine internal brine concentration, as long as the establishment proposes it and submits data and other information to establish its sufficiency to the Director of the Processed Products Inspection Division;

(iii) Each sample shall weigh no less than 100 grams;

(iv) The samples shall be combined as one composite sample and sealed in a water vapor proof container;

(v) The composite sample shall be submitted to a laboratory accredited under the provisions of § 318.21 to be analyzed for salt and water content using methods from the "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC)," 15th Edition, 1990, section 983.18 (page 931) and section 971.19 (page 933) which are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, suite 400–BW, 2200 Wilson Boulevard, Arlington, VA 22201–3301. Copies may be inspected at the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment shall freeze the composite sample immediately after the samples are combined;

(vi) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance shall be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested shall be held until the establishment brings the lot into compliance by further processing.

(2) To maintain compliance, the establishment shall take samples, have the samples analyzed, and perform the brine calculations as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance shall not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment shall develop and propose steps acceptable to FSIS to ensure that the process is corrected.

(3) Accredited laboratory results and the brine calculations shall be placed on file in the establishment and available to Program employees for review.

* * * * *

PART 320—[AMENDED]

3. The authority for part 320 continues to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 930, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*

4. Paragraph (b)(7) is added to § 320.1 to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(7) Sample results and calculation results as required by processing procedures to destroy trichinae in § 318.10(c)(3)(iv) (Methods 5 and 6).

* * * * *

Done at Washington, DC on: May 8, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

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